Practitioner's Docket No. 870-003-123

CHAPTER II

Preliminary Classification:
Proposed Class: 604
Subclass: 192
NOTE: "All applicants are requested to include a preliminary classification on newly filed patent applications. The preliminary classification, preferably class and subclass designations, should be identified in the upper right-hand corner of the letter of transmittal accompanying the application papers, for example 'Proposed Class 2, subclass 129.'" M.P.E.P., § 601, 7th ed.

TRANSMITTAL LETTER TO THE UNITED STATES ELECTED OFFICE (EO/US)

(ENTRY INTO U.S. NATIONAL PHASE UNDER CHAPTER II)

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/EP98/07230	11 November 1998	19 November 1997

TITLE OF INVENTION
Needle Arrangement

APPLICANT(S)
Gabriel & Polzin

Box PCT
Assistant Commissioner for Patents
Washington D.C. 20231

ATTENTION: EO/US

CERTIFICATION UNDER 37 C.F.R. § 1.10*
(Express Mail label number is mandatory.)
(Express Mail certification is optional.)

I hereby certify that this Transmittal Letter and the papers indicated as being transmitted therewith is being deposited with the United States Postal Service on this date May 4, 2000, in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number EL 508 861 279 US, addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

Ellen C. LaPak
(type or print name of person mailing paper)
Ellen C LaPak
Signature of person mailing paper

WARNING: *Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. § 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.*

***WARNING:** Each paper or fee filed by "Express Mail" **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. § 1.10(b).*
*"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.*

NOTE: To avoid abandonment of the application, the applicant shall furnish to the USPTO, not later than 20 months from the priority date: (1) a copy of the international application, unless it has been previously communicated by the International Bureau or unless it was originally filed in the USPTO; and (2) the basic national fee (see 37 C.F.R. § 1.492(a)). The 30-month time limit may not be extended. 37 C.F.R. § 1.495.

***WARNING:** Where the items are those which can be submitted to complete the entry of the international application into the national phase are subsequent to 30 months from the priority date the application is still considered to be in the international state and if mailing procedures are utilized to obtain a date the express mail procedure of 37 C.F.R. § 1.10 must be used (since international application papers are not covered by an ordinary certificate of mailing—See 37 C.F.R. § 1.8.*

NOTE: Documents and fees must be clearly identified as a submission to enter the national state under 35 U.S.C. § 371 otherwise the submission will be considered as being made under 35 U.S.C. § 111. 37 C.F.R. § 1.494(f).

I. Applicant herewith submits to the United States Elected Office (EO/US) the following items under 35 U.S.C. § 371:

a. ☒ This express request to immediately begin national examination procedures (35 U.S.C. § 371(f)).

b. ☐ The U.S. National Fee (35 U.S.C. § 371(c)(1)) and other fees (37 C.F.R. § 1.492) as indicated below:

2. Fees

CLAIMS FEE	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
☐*	TOTAL CLAIMS 16	−20=		× $18.00=	$ 0.00
	INDEPENDENT CLAIMS 1	−3=		× $78.00=	0.00
	MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ $260.00	
BASIC FEE**	☐ U.S. PTO WAS INTERNATIONAL PRELIMINARY EXAMINATION AUTHORITY Where an international preliminary examination fee as set forth in § 1.482 has been paid on the international application to the U.S. PTO: ☐ and the international preliminary examination report states that the criteria of novelty, inventive step (non-obviousness) and industrial activity, as defined in PCT Article 33(1) to (4) have been satisfied for all the claims presented in the application entering the national stage (37 C.F.R. § 1.492(a)(4)) ..... $96.00 ☐ and the above requirements are not met (37 C.F.R. § 1.492(a)(1)) ..... $670.00 ☒ U.S. PTO WAS NOT INTERNATIONAL PRELIMINARY EXAMINATION AUTHORITY Where no international preliminary examination fee as set forth in § 1.482 has been paid to the U.S. PTO, and payment of an international search fee as set forth in § 1.445(a)(2) to the U.S. PTO: ☐ has been paid (37 C.F.R. § 1.492(a)(2)) ..... $760.00 ☐ has not been paid (37 C.F.R. § 1.492(a)(3)) ..... $970.00 ☒ where a search report on the international application has been prepared by the European Patent Office or the Japanese Patent Office (37 C.F.R. § 1.492(a)(5)) $840.00				840.00
	Total of above Calculations				= 840.00
SMALL ENTITY	Reduction by 1/2 for filing by small entity, if applicable. Affidavit must be filed also. (note 37 C.F.R. § 1.9, 1.27, 1.28)				−
	Subtotal				840.00
	Total National Fee				$840.00
	Fee for recording the enclosed assignment document $40.00 (37 C.F.R. § 1.21(h)). (See Item 13 below). See attached "ASSIGNMENT COVER SHEET".				40.00
TOTAL	Total Fees enclosed				$880.00

*See attached Preliminary Amendment Reducing the Number of Claims.

i. ☒ A check in the amount of $890.00 to cover the above fees is enclosed.

ii. ☒ Please charge Account No. 23-0442 in the amount of $ any deficiency. A duplicate copy of this sheet is enclosed.

***WARNING:** *"To avoid abandonment of the application the applicant shall furnish to the United States Patent and Trademark Office not later than the expiration of 30 months from the priority date: * * * (2) the basic national fee (see § 1.492(a)). The 30-month time limit may not be extended." 37 C.F.R. § 1.495(b).*

WARNING: *If the translation of the international application and/or the oath or declaration have not been submitted by the applicant within thirty (30) months from the priority date, such requirements may be met within a time period set by the Office. 37 C.F.R. § 1.495(b)(2). The payment of the surcharge set forth in § 1.492(e) is required as a condition for accepting the oath or declaration later than thirty (30) months after the priority date. The payment of the processing fee set forth in § 1.492(f) is required for acceptance of an English translation later than thirty (30) months after the priority date. Failure to comply with these requirements will result in abandonment of the application. The provisions of § 1.136 apply to the period which is set. Notice of Jan. 3, 1993, 1147 O.G. 29 to 40.*

3. ☒ A copy of the International application as filed (35 U.S.C. § 371(c)(2)):

NOTE: Section 1.495 (b) was amended to require that the basic national fee and a copy of the international application must be filed with the Office by 30 months from the priority date to avoid abandonment. "The International Bureau normally provides the copy of the international application to the Office in accordance with PCT Article 20. At the same time, the International Bureau notifies applicant of the communication to the Office. In accordance with PCT Rule 47.1, that notice shall be accepted by all designated offices as conclusive evidence that the communication has duly taken place. Thus, if the applicant desires to enter the national stage, the applicant normally need only check to be sure the notice from the International Bureau has been received and then pay the basic national fee by 30 months from the priority date." Notice of Jan. 7, 1993, 1147 O.G. 29 to 40, at 35-36. See item 14c below.

a. ☒ is transmitted herewith.

b. ☐ is not required, as the application was filed with the United States Receiving Office.

c. ☐ has been transmitted

i. ☐ by the International Bureau.
Date of mailing of the application (from form PCT/1B/308): _____.

ii. ☐ by applicant on _____ *(Date).*

4. ☒ A translation of the International application into the English language (35 U.S.C. § 371(c)(2)):

a. ☒ is transmitted herewith.

b. ☐ is not required as the application was filed in English.

c. ☐ was previously transmitted by applicant on _____ *(Date).*

d. ☐ will follow.

5. ☒ Amendments to the claims of the International application under PCT Article 19 (35 U.S.C. § 371(c)(3)):

NOTE: The Notice of January 7, 1993 points out that 37 C.F.R. § 1.495(a) was amended to clarify the existing and continuing practice that PCT Article 19 amendments must be submitted by 30 months from the priority date and this deadline may not be extended. The Notice further advises that: "The failure to do so will not result in loss of the subject matter of the PCT Article 19 amendments. Applicant may submit that subject matter in a preliminary amendment filed under section 1.121. In many cases, filing an amendment under section 1.121 is preferable since grammatical or idiomatic errors may be corrected." 1147 O.G. 29-40, at 36.

a. ☐ are transmitted herewith.

b. ☐ have been transmitted

i. ☐ by the International Bureau.
Date of mailing of the amendment (from form PCT/1B/308): _____.

ii. ☐ by applicant on _____ *(Date).*

c. ☒ have not been transmitted as A PRELIMINARY AMENDMENT IS ENCLOSED INSTEAD.

i. ☐ applicant chose not to make amendments under PCT Article 19.
Date of mailing of Search Report (from form PCT/ISA/210.): _____.

ii. ☐ the time limit for the submission of amendments has not yet expired. The amendments or a statement that amendments have not been made will be transmitted before the expiration of the time limit under PCT Rule 46.1.

6. ☒ A translation of the amendments to the claims under PCT Article 19 (38 U.S.C. § 371(c)(3)):

a. ☐ is transmitted herewith.

b. ☐ is not required as the amendments were made in the English language.

c. ☒ has not been transmitted for reasons indicated at point 5(c) above.

7. ☒ A copy of the international examination report (PCT/IPEA/409)

☒ is transmitted herewith.

☐ is not required as the application was filed with the United States Receiving Office.

8. ☒ Annex(es) to the international preliminary examination report

a. ☒ is/are transmitted herewith.

b. ☐ is/are not required as the application was filed with the United States Receiving Office.

9. ☒ A translation of the annexes to the international preliminary examination report

a. ☒ is transmitted herewith.

b. ☐ is not required as the annexes are in the English language.

10. ☒ An oath or declaration of the inventor (35 U.S.C. § 371(c)(4)) complying with 35 U.S.C. § 115

a. ☐ was previously submitted by applicant on _____ *(Date)*.

b. ☒ is submitted herewith, and such oath or declaration

i. ☒ is attached to the application.

ii. ☐ identifies the application and any amendments under PCT Article 19 that were transmitted as stated in points 3(b) or 3(c) and 5(b); and states that they were reviewed by the inventor as required by 37 C.F.R. § 1.70.

c. ☐ will follow.

II. Other document(s) or information included:

11. ☒ An International Search Report (PCT/ISA/210) or Declaration under PCT Article 17(2)(a):

a. ☒ is transmitted herewith.

b. ☐ has been transmitted by the International Bureau. Date of mailing (from form PCT/IB/308): _____.

c. ☐ is not required, as the application was searched by the United States International Searching Authority.

d. ☐ will be transmitted promptly upon request.

e. ☐ has been submitted by applicant on _____ *(Date)*.

12. ☒ An Information Disclosure Statement under 37 C.F.R. §§ 1.97 and 1.98:

a. ☒ is transmitted herewith.

Also transmitted herewith is/are:

☒ Form PTO-1449 (PTO/SB/08A and 08B).

☒ Copies of citations listed.

b. ☐ will be transmitted within THREE MONTHS of the date of submission of requirements under 35 U.S.C. § 371(c).

c. ☐ was previously submitted by applicant on _____ *(Date)*.

13. ☒ An assignment document is transmitted herewith for recording.

A separate ☐ "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or ☒ FORM PTO 1595 is also attached.

_____

_____

_____

14. ☒ Additional documents:

a. ☐ Copy of request (PCT/RO/101)

b. ☒ International Publication No. WO 99/25402

i. ☒ Specification, claims and drawing

ii. ☐ Front page only

c. ☒ Preliminary amendment (37 C.F.R. § 1.121)

d. ☐ Other

_____

_____

_____

15. ☒ The above checked items are being transmitted

a. ☒ before 30 months from any claimed priority date.

b. ☐ after 30 months.

16. ☐ Certain requirements under 35 U.S.C. § 371 were previously submitted by the applicant on _____, namely:

_____

_____

_____

_____

_____

AUTHORIZATION TO CHARGE ADDITIONAL FEES

WARNING: *Accurately count claims, especially multiple dependant claims, to avoid unexpected high charges if extra claims are authorized.*

NOTE: "A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. § 1.136(a)(3).

NOTE: "Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. § 1.26(a).

☒ The Commissioner is hereby authorized to charge the following additional fees that may be required by this paper and during the entire pendency of this application to Account No. 23-0442

☒ 37 C.F.R. § 1.492(a)(1), (2), (3), and (4) (filing fees)

WARNING: *Because failure to pay the national fee within 30 months without extension (37 C.F.R. § 1.495(b)(2)) results in abandonment of the application, it would be best to always check the above box.*

☒ 37 C.F.R. § 1.492(b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. § 1.492(d)), it might be best not to authorize the PTO to charge additional claim fees, except possible when dealing with amendments after final action.

☐ 37 C.F.R. § 1.17 (application processing fees)

☐ 37 C.F.R. § 1.17(a)(1)–(5) (extension fees pursuant to § 1.136(a).

☐ 37 C.F.R. § 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. § 1.311(b))

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 C.F.R. § 1.311(b).

NOTE: 37 C.F.R. § 1.28(b) requires "Notification of any change in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying . . . issue fee." From the wording of 37 C.F.R. § 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

☐ 37 C.F.R. § 1.492(e) and (f) (surcharge fees for filing the declaration and/or filing an English translation of an International Application later than 30 months after the priority date).

Milton Oliver

SIGNATURE OF PRACTITIONER

Reg. No.: 28,333

Milton Oliver

(type or print name of practitioner)

Tel. No.: (203) 261-1234

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IN THE U.S. PATENT & TRADEMARK OFFICE

Applicants: GABRIEL & POLZIN

Serial #: 09/_____ = § 371 of PCT/EP98/07230

Filed: 4 MAY 2000 (HEREWITH)

Title: NEEDLE ARRANGEMENT

Art Unit: _____ Examiner: Not yet assigned

PRELIMINARY AMENDMENT TO PCT APPLICATION

Assistant Commissioner for Patents
Washington, D.C. 20231

4 MAY 2000

Sir:

Prior to counting the claims,

please amend the application as follows:

IN THE SPECIFICATION:

Page 1, before line 1, insert --FIELD OF THE INVENTION:--.

Page 1, after line 1, insert --BACKGROUND:--.

Page 1, line 2, after "758 A1" insert --, HJERTMAN et al.--.

Page 1, after line 7, insert --SUMMARY OF THE INVENTION:--.

Page 1, cancel line 11 and

replace with --providing a compressible spring surrounding the needle, and a generally cylindrical open-ended first cap which fits over the spring.--.

Page 1, line 18, cancel line 18 and replace with

--to make the spring of plastic material, and form it integrally with a hollow needle carrier.--.

Page 1, cancel line 23 and replace with:

--to provide a second covering cap which surrounds the first cap, the needle, and the needle carrier, and is sealed closed by a peelable foil, thereby keeping the surrounded elements sterile until the user peels off the foil.--.

"Express Mail" Mailing Label No. **EL 508 861 279 US**
Date of Deposit: **MAY 4, 2000**

I hereby certify that this document is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Ellen C. LaPak

Ellen C. LaPak

Page 2, after line 7, insert --BRIEF FIGURE DESCRIPTION:--.

Page 3, before line 1, insert --DETAILED DESCRIPTION:--.

Page 7, line 1, change "CLAIMS" to

--WHAT IS CLAIMED IS:--.

Page 13, after "ABSTRACT", insert --OF THE DISCLOSURE--.

IN THE CLAIMS:

1. (Amended) A needle arrangement for an injection device (16),

having a hollow needle carrier (10) on which a hollow needle (12) is mounted and which is configured for mounting on an injection device (16);

having a first cap (32) which is arranged on the hollow needle carrier (10) and is displaceable[y] approximately parallel to the longitudinal extension of the hollow needle (12) between a distal and a proximal end position, is formed [equipped] at its proximal end segment with a passthrough opening (42) for the hollow needle (12), and in its proximal end position substantially conceals the hollow needle (12);

having a compression spring (26), arranged between the hollow needle carrier (10) and the first cap (32), for displacing the first cap (32) into its proximal end position; [and]

having a second cap (66) adapted to surround said displaceable first cap (32), said hollow needle (12) and said hollow needle carrier (18), and having a user-removable protective barrier (71) closing off an open side of said second cap, whereby said second cap (66) and said protective barrier together form a sterile enclosure around said first cap (32), said hollow needle (12) and said needle carrier (10). [a stop (58, 60, 58', 60'), provided on the outer side (36) of the hollow needle carrier (10) for the distal end position of the first cap (32), which coacts with a distal end segment (53) of the first cap (32) and determines the penetration depth (D) of the hollow needle (12).]

2. (Amended) The needle arrangement as defined in claim 1, [in which the stop (56, 58, 60, 56', 58', 60') is modifiable] wherein said hollow needle carrier (10) is formed with an internal thread (20) for engagement with an external thread (18) formed on a surface of an associated injection device (16).

3. (Amended) The needle arrangement as defined in claim 1 [or 2, in which at least two stop elements (58, 60, 58', 60'), each joined to the hollow needle carrier (10) by a defined break point (76), are provided on the outer side (36) of the hollow needle carrier (10)]. wherein said cover cap (66) has a form adapted for transfer of torque to said hollow needle carrier (10).

4. (Amended) The needle arrangement as defined in claim 3,
[in which the defined break point (76) serves, after it breaks, as axial guide for the displacement of the first cap (32) relative to the hollow needle carrier (10)] wherein said cover cap (66) is shaped for form-locking engagement with said hollow needle carrier (10).

5. (Amended) The needle arrangement according to claim 1,
wherein said user-removable protective barrier (71) is a peelable foil bonded across said open side of said second cap (66). [as defined in one or more of the foregoing claims, in which the first cap (32) is arranged displaceably on a substantially cylindrical circumferential surface (36) of the hollow needle carrier (10); and
a rotation preventer (44, 45) is provided which at least almost prevents any rotation between the hollow needle carrier (10) and the first cap (32).]

6. The needle arrangement according to claim 1, wherein
an outer surface (36) of said hollow needle carrier (10) is formed with at least two stop elements (58, 60, 58', 60') serving to limit axial displacement of said first cap (32), said stop elements being frangible from said needle carrier at respective breakpoints (76) formed therein.
[as defined in claim 5, in which the rotation preventer (44, 45) has at least one longitudinal groove (44) which is provided on the first cap (32) or hollow needle carrier (10), and
a complementary projection (45) engaging thereinto which is provided on the corresponding mating part, i.e. the hollow needle carrier or first cap.]

7. (Amended) The needle arrangement according to claim 6, wherein
the cover cap (66) has a form adapted to influence at least one stop member (58, 60, 58', 60') formed on an outer surface of said hollow needle carrier (10) in order to set a penetration depth (D) of said needle.
[as defined in one or more of claims 1 through 6, in which the spring is configured as a plastic spring (26).]

8. (Amended) The needle arrangement as defined in claim 7, wherein
the at least one stop member (58, 60) is mounted on the hollow needle carrier (10) via a defined breakpoint (76) at which said stop member can be broken off by a rotational motion (74) of the covering cap (66, 66') brought into engagement with said stop member. [in which the plastic spring (26) is configured integrally with the hollow needle carrier (10).]

9. (Amended) The needle arrangement as defined in claim 6, wherein said breakpoint serves as a axial guide for displacement of said first cap (32) relative to said hollow needle carrier (10). [7 or 8, in which the plastic spring (26) is equipped at its proximal end with a ring (28) which is in contact against the first cap (32) and acts upon it in the proximal direction.]

10. (Amended) The needle arrangement according to claim 1, wherein the first cap (32) is arranged displaceably on a substantially cylindrical circumferential surface (36) of the hollow needle carrier (10), and a rotation preventer (44, 45) is provided between the hollow needle carrier (10) and the first cap (32).
[as defined in claim 9, in which the ring (28) is configured integrally with the plastic spring (26).]

11. (Amended) The needle arrangement according to claim 10, wherein said rotation preventer includes a longitudinal groove (44), formed on one of said first cap (32) and said needle carrier (10), and a complementary projection (45), adapted to engage in said groove (44), formed on the other of said first cap (32) and said needle carrier (10).
[as defined in one or more of the foregoing claims, in which a covering cap (66) is provided which substantially surrounds the outer circumference (35) of the first cap (32).]

12. (Amended) The needle arrangement according to claim 1, wherein said compression spring (26) is formed of plastic material.
[as defined in claim 11, in which the covering cap (66) extends over the hollow needle carrier (10); and rotation prevention is provided between it and the hollow needle carrier (10).]

13. (Amended) The needle arrangement as defined in claim 12, wherein said plastic spring is formed integrally with said needle carrier (10).
[in which the rotation preventer (60, 70) has a longitudinal groove (70) which is provided on the covering cap (66) or the hollow needle carrier (10), and a complementary projection (60) engaging thereinto which is provided on the corresponding mating part, i.e. on the hollow needle carrier or covering cap.]

14. (Amended) The needle arrangement according to claim 12, wherein said plastic spring (26) has a proximal end formed as a ring (32), said ring engaging against said first cap (32) and urging said cap in a proximal direction.
[as defined in one or more of claims 11 through 13, in which the covering cap (66) is sealed in sterile fashion on its open side by a tear-off sealing member (71).]

15. (Amended) The needle arrangement as defined in [one or more of] claim[s 11 through] 14, wherein the ring (28) is formed integrally with said plastic spring (26).
[in which the covering cap (66) is configured so as to influence at least one stop member (58, 60, 58', 60') of the stop provided on the outer side of the hollow needle carrier (10) in order to adjust the penetration depth (D).]

16. (Amended) The needle arrangement as defined in claim 12, wherein the plastic spring (26) includes a pair of helical spring elements (26a, 26b), each formed integrally with said hollow needle carrier (10).
[15, in which the at least one stop member (58, 60) of the stop provided on the outer side of the hollow needle carrier (10) is mounted on the hollow needle carrier (10) via a defined break point (76) which can be broken off by way of a rotary motion (74) of the covering cap (66, 66') brought into engagement with said stop member.]

Cancel claims 17-33, without prejudice.

REMARKS

Applicants have made the foregoing amendments to place the PCT application text in customary US format, so that all the claims can be considered on their merits. All multiple dependencies have been cancelled. The foreign document mentioned in the specification is included in the Information Disclosure Statement filed herewith. If the Patent Office notes any remaining informalities which would prevent or hinder examination on the merits, a telephone call to Applicants' counsel is requested.

Respectfully submitted,

Milton Oliver

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Att. Docket No. 870-003-123

NEEDLE ARRANGEMENT

The invention relates to a needle arrangement for an injection device.

A needle arrangement of this kind is known from EP 0 749 758 A1. In it, a hollow needle that is mounted on a hollow needle holder is used. The latter is screwed onto an external thread at the proximal end of the injection device. A special apparatus which makes the hollow needle invisible to the user, so as to eliminate his or her anxiety regarding injections, is then slid over this hollow needle.

It is the object of the invention to make available a new needle arrangement for an injection device.

According to the invention, this object is achieved by the subject matter of Claim 1. A needle arrangement of this kind is very easy to utilize, since in practice it uses nothing more than a replaceable hollow needle. Easy adjustment of the penetration depth is also achieved, since the necessary penetration depth may be different depending on the patient's constitution. In this instance, it can be adjusted easily and obviously.

Another manner of achieving the stated object is evident from the subject matter of Claim 18. An arrangement of this kind has only a few parts and thus can be produced very economically. It can be used by the patient in a simple, easily understandable fashion.

A further manner of achieving the stated object is evident from the subject matter of Claim 30. A needle arrangement of this kind can very easily be kept sterile until used. The covering cap is usable as an assembly aid, additionally facilitating use by the patient.

Each time the patient thrusts the hollow needle in prior to an

injection, the displaceable cap is displaced in the distal direction against the force of the spring, and when the hollow needle is pulled out it moves back into its proximal end position under the action of the spring, so that the patient does not see the hollow needle during the entire injection procedure. Because of the detachable mounting on the injection device, a needle arrangement of this kind can very easily be replaced, after an injection, with a new, sterile needle arrangement.

Further details and advantageous developments of the invention are evident from the exemplary embodiment, which is described below and depicted in the drawings and is in no way to be understood as a limitation of the invention, and from the dependent claims. In the drawings:

FIG. 1 is a longitudinal section through a preferred embodiment of a needle arrangement according to the present invention, in an exploded and greatly magnified depiction;

FIG. 2 shows a view similar to that of FIG. 1 but in the assembled state, the hollow needle being concealed by the arrangement;

FIG. 3 shows a view similar to that of FIG. 2 but with the needle thrust in, the penetration depth being labeled D;

FIG. 4 shows a view similar to that of FIG. 2, additionally depicting an outer covering cap 66 which serves to encase the needle arrangement in sterile fashion;

FIG. 5 shows a view of a complete, packaged needle arrangement according to a preferred embodiment of the invention;

FIG. 6 is a plan view looking in the direction of arrow VI of FIG. 5;

FIG. 7 is a view showing the adjustment of the penetration depth by way of the external covering cap 66;

FIG. 8 is a sectional view along line A-A of FIG. 7;

FIG. 9 is a sectional view along line B-B of FIG. 7; and

FIG. 10 is a sectional view through a defined breakpoint for a stop element, viewed along line C-C of FIG. 7.

In the description that follows, the terms "proximal" and "distal" will be used in the manner usual in medicine, to wit:

"proximal" = facing toward the patient (the end of the injection device having the needle);

"distal" = facing away from the patient.

FIG. 1 shows, on the left, a hollow needle carrier 10 made of a suitable plastic, e.g. polyethylene. Secured in this is a hollow needle (injection needle) 12 whose distal end 14 serves to pierce through the rubber membrane (not depicted) on the reservoir of an injection device 16 that is indicated only schematically in FIGS. 2 and 3.

An inner thread 20 of hollow needle 10, which is delimited in the proximal direction by a shoulder 22 serving as a stop, provides detachable mounting on an external thread 18 at the proximal end of injection device 16.

The proximal segment of hollow needle 12 is labeled 24. Extending concentrically around it, in the arrangement as shown in FIG. 1, is a plastic spring 26 that can be configured integrally with hollow needle carrier 10 and that here comprises two helical springs or spirals 26a, 26b, offset 180°, which each transition at their proximal end into a ring 28 with which they can also be integrally configured. Alternatively a separate spring, for example made of metal, could also be used here.

A first sleeve or cap 32 has a substantially cylindrical segment 34 whose cylindrical outer side is labeled 33 and whose cylindrical inner side 35 is configured for sliding displacement on the (also cylindrical)

circumference 36 of hollow needle carrier 10. First cap 32 furthermore has at its proximal end a base 40 in whose center is located a recess 42 through which proximal end 24 of hollow needle 12 can pass during an injection, as shown in FIG. 3.

First cap 32 has on its inner side 35 a total of three longitudinal grooves 44, only two of which are visible in FIG. 1, uniformly distributed on the circumference and providing axial guidance, i.e. rotation prevention. They coact with three projections 45, complementary thereto, on the cylindrical outer circumference 36 of hollow needle carrier 10, as clearly shown by FIGS. 2 and 3.

First cap 32 furthermore has three barbs 46 on its inner circumference 35. These barbs are also uniformly distributed on the circumference, and coact with three corresponding complementary barbs 48 on outer circumference 36 of hollow needle 10, only one of which is visible in FIG. 1. During assembly, barbs 46 slide over barbs 48 so that parts 10 and 32 are joined to one another nondetachably but axially displaceably; barbs 46, 48 form a stop in the proximal direction, as depicted in FIG. 2, and grooves 44 coact with the complementary projections 45 to provide rotation prevention for first cap 32, so that the latter cannot rotate relative to hollow needle carrier 10.

As clearly shown in FIGS. 1 through 3, there is located on outer circumference 36 of hollow needle carrier 10 a stop arrangement 50 against whose proximal shoulder 52 (as shown in FIG. 3) first cap 32 comes to rest with its distal end 53 when hollow needle 12 is thrust with its proximal end 24 into a body part 54 (indicated only schematically).

Stop arrangement 50 has here a distal stop element 56, a central stop element 58, and a proximal stop element 60. At least proximal stop element 60 and central stop element 58 are each joined integrally to hollow needle carrier 10 by way of a defined break point 76 (FIG. 10), and consequently can be broken off from hollow needle carrier 10 by the user. This increases insertion depth D (FIG. 3) of the proximal hollow needle portion 24. Thus either it is possible to break off only stop element 60, so that first cap

32 then comes to rest against a shoulder 61 when hollow needle 12 is thrust in; or both stop elements 58 and 60 can be broken off, in which case first cap 32 then comes to rest against a shoulder 62 when hollow needle 12 is thrust in. In the latter case, the maximum penetration depth is attained.

FIG. 4 shows, at left, hollow needle carrier 10 on whose circumference stop elements 56, 58, 60 and 56, 58', 60, 56", etc. are arranged at uniform spacings of 120°. FIG. 6 shows the three stop elements 56, 56', and 56" in a plan view according to arrow VI of FIG. 5.

FIG. 4 shows that an outer covering cap 66, which provides sterile covering of the needle arrangement, is also provided. Outer covering cap 66 is depicted in FIG. 4 partially in longitudinal section, and it is evident that its cylindrical inner recess 68, which in the case of the complete needle arrangement shown in FIGS. 5 and 6 is slid over the cylindrical outer side 33 of first cap 32, has three longitudinal grooves 70 which are distributed uniformly on the circumference of inner recess 68 and are dimensioned such that they can be slid over stop elements 56, 58, 60, 56', 58', 60', 56" etc., as is particularly clearly evident from FIG. 6.

FIG. 5 also shows a protective film 71 with which, in the complete needle arrangement, the opening (FIG. 5, left) of outer covering cap 66 can be sealed in sterile fashion. This film is welded on or adhesively bonded on, and is torn off before use. Film 71 is not depicted in FIG. 6.

FIG. 7 shows how outer covering cap 66 can be slid axially onto first cap 32 in the direction of arrow 72, arriving at a position 66' which is indicated in FIG. 7 with dot-dash lines and is depicted in section in FIG. 8, and in which its longitudinal grooves 70 are in engagement with stop elements 60, 60', 60". If outer covering cap 66 is then rotated in the direction of rotation arrow 74 depicted in FIG. 7, stop elements 60, 60', 60" are broken off along their defined break points 76 (cf. FIG. 10), i.e. penetration depth D (FIG. 3) is correspondingly increased in the manner already described above. In the same manner, it is also possible to break

off both stop elements 58, 60 (correspondingly 58', 60', etc.), and thereby to increase penetration depth D even further.

What is described is thus a needle arrangement for an injection device 16. It has a hollow needle carrier 10 on which a hollow needle 12 is mounted and which is configured for detachable mounting on injection device 16. The arrangement has a cap 32 that is arranged on hollow needle carrier 10 displaceably approximately parallel to the longitudinal extension of hollow needle 12, is equipped at its proximal end segment with a passthrough opening 42 for hollow needle 12, and in its proximal end position substantially conceals hollow needle 12. A compression spring 26 is arranged between hollow needle carrier 10 and cap 32 in order to displace cap 32 into its proximal end position. Also provided is a covering cap 66 which surrounds the displaceable cap 32, hollow needle 12, and hollow needle carrier 10, and on its open side is sealed in sterile fashion by a tear-off sealing member 71. A needle arrangement of this kind can easily be replaced after an injection. It improves compliance because the patient does not at any time see hollow needle 12. The compression spring can be configured as plastic spring 26. It is preferably integral with hollow needle carrier 10, which simplifies manufacture.

Many other variants and modifications are, of course, also possible within the scope of the present invention.

CLAIMS

1. A needle arrangement for an injection device (16),

having a hollow needle carrier (10) on which a hollow needle (12) is mounted and which is configured for mounting on an injection device (16);

having a first cap (32) which is arranged on the hollow needle carrier (10) and displaceably approximately parallel to the longitudinal extension of the hollow needle (12) between a distal and a proximal end position, is equipped at its proximal end segment with a passthrough opening (42) for the hollow needle (12), and in its proximal end position substantially conceals the hollow needle (12);

having a compression spring (26), arranged between the hollow needle carrier (10) and the first cap (32), for displacing the first cap (32) into its proximal end position; and

having a stop (58, 60, 58', 60'), provided on the outer side (36) of the hollow needle carrier (10) for the distal end position of the first cap (32), which coacts with a distal end segment (53) of the first cap (32) and determines the penetration depth (D) of the hollow needle (12).

2. The needle arrangement as defined in Claim 1, in which the stop (56, 58, 60, 56', 58', 60') is modifiable.

3. The needle arrangement as defined in Claim 1 or 2, in which at least two stop elements (58, 60, 58', 60'), each joined to the hollow needle carrier (10) by a defined break point (76), are provided on the outer side (36) of the hollow needle carrier (10).

4. The needle arrangement as defined in Claim 3, in which the defined break point (76) serves, after it breaks, as axial guide for the displacement of the first cap (32) relative to the hollow needle carrier (10).

5. The needle arrangement as defined in one or more of the foregoing

claims, in which the first cap (32) is arranged displaceably on a substantially cylindrical circumferential surface (36) of the hollow needle carrier (10); and

a rotation preventer (44, 45) is provided which at least almost prevents any rotation between the hollow needle carrier (10) and the first cap (32).

6. The needle arrangement as defined in Claim 5, in which the rotation preventer (44, 45) has at least one longitudinal groove (44) which is provided on the first cap (32) or hollow needle carrier (10), and

a complementary projection (45) engaging thereinto which is provided on the corresponding mating part, i.e. the hollow needle carrier or first cap.

7. The needle arrangement as defined in one or more of Claims 1 through 6, in which the spring is configured as a plastic spring (26).

8. The needle arrangement as defined in Claim 7, in which the plastic spring (26) is configured integrally with the hollow needle carrier (10).

9. The needle arrangement as defined in Claim 7 or 8, in which the plastic spring (26) is equipped at its proximal end with a ring (28) which is in contact against the first cap (32) and acts upon it in the proximal direction.

10. The needle arrangement as defined in Claim 9, in which the ring (28) is configured integrally with the plastic spring (26).

11. The needle arrangement as defined in one or more of the foregoing claims, in which a covering cap (66) is provided which substantially surrounds the outer circumference (35) of the first cap (32).

12. The needle arrangement as defined in Claim 11, in which the covering cap (66) extends over the hollow needle carrier (10); and
rotation prevention is provided between it and the hollow needle

carrier (10).

13. The needle arrangement as defined in Claim 12, in which the rotation preventer (60, 70) has a longitudinal groove (70) which is provided on the covering cap (66) or the hollow needle carrier (10), and

a complementary projection (60) engaging thereinto which is provided on the corresponding mating part, i.e. on the hollow needle carrier or covering cap.

14. The needle arrangement as defined in one or more of Claims 11 through 13, in which the covering cap (66) is sealed in sterile fashion on its open side by a tear-off sealing member (71).

15. The needle arrangement as defined in one or more of Claims 11 through 14, in which the covering cap (66) is configured so as to influence at least one stop member (58, 60, 58', 60') of the stop provided on the outer side of the hollow needle carrier (10) in order to adjust the penetration depth (D).

16. The needle arrangement as defined in Claim 15, in which the at least one stop member (58, 60) of the stop provided on the outer side of the hollow needle carrier (10) is mounted on the hollow needle carrier (10) via a defined break point (76) which can be broken off by way of a rotary motion (74) of the covering cap (66, 66') brought into engagement with said stop member.

17. The needle arrangement as defined in one or more of the foregoing claims, in which an inner thread (20) is provided on the hollow needle carrier (10) for detachable mounting on an outer thread (18) of an associated injection device (16).

18. A needle arrangement for an injection device (16), having a hollow needle carrier (10) on which a hollow needle (12) is mounted and which is configured for mounting on an injection device (16);

having a first cap (32) arranged on the hollow needle carrier (10)

displaceably approximately parallel to the longitudinal extension of the hollow needle (12),

which is equipped at its proximal end segment with a passthrough opening (42) for the hollow needle (12), and

in its proximal end position substantially conceals said hollow needle (12); and

having a compression spring, arranged between the hollow needle carrier (10) and first cap (32), which is configured as a plastic spring (26) and is configured integrally with the hollow needle carrier (10).

19. The needle arrangement as defined in Claim 18, in which the plastic spring (26) is equipped, at its end region facing away from the hollow needle carrier (10), with a ring (28) that acts upon the first cap (32) in the direction away from the hollow needle carrier (10).

20. The needle arrangement as defined in Claim 19, in which the ring (28) is configured integrally with the plastic spring (26).

21. The needle arrangement as defined in one or more of Claims 18 through 20, in which the plastic spring (26) has two helical spring elements (26a, 26b), each of which is configured integrally with the hollow needle carrier (10).

22. The needle arrangement as defined in one or more of Claims 18 through 21, in which the plastic spring (26) is arranged substantially concentrically with the hollow needle (12).

23. The needle arrangement as defined in one or more of Claims 18 through 22, in which the first cap (32) is arranged displaceably on a substantially cylindrical circumferential surface (36) of the hollow needle carrier (10), and a rotation preventer (44, 45) is provided between the hollow needle carrier (10) and the first cap (32).

24. The needle arrangement as defined in Claim 23, in which the rotation preventer (44, 45) has at least one longitudinal groove (44) that is provided on the first cap (32) or hollow needle carrier (10), and

a complementary projection (45) engaging thereinto which is provided on the corresponding mating part, i.e. hollow needle carrier or first cap.

25. The needle arrangement as defined in one or more of Claims 18 through 24, in which a covering cap (66) is provided that can be slid onto the first cap (32) and thereby substantially surrounds its outer circumference (35).

26. The needle arrangement as defined in Claim 25, in which the covering cap (66) extends over the hollow needle carrier (10), and

a rotation preventer is provided between it and the hollow needle carrier (10).

27. The needle arrangement as defined in Claim 26, in which the rotation preventer (60, 70) has a longitudinal groove (70) which is provided on the covering cap (66) or on the hollow needle carrier (10), and

a complementary projection (60) engaging thereinto which is provided on the corresponding mating part, i.e. on the hollow needle carrier or covering cap.

28. The needle arrangement as defined in one or more of Claims 25 through 27, in which the covering cap (66) is sealed in sterile fashion on its open side by a tear-off sealing member (71).

29. The needle arrangement as defined in one or more of Claims 18 through 28, in which an internal thread (20) is provided on the hollow needle carrier (10) for mounting on an external thread (18) of an associated injection device (16).

30. A needle arrangement for an injection device (16),

having a hollow needle carrier (10) on which a hollow needle (12) is mounted and which is configured for mounting on the injection device (16);

having a cap (32) which is arranged on the hollow needle carrier (10) displaceably approximately parallel to the longitudinal extension

of the hollow needle (12), has at its proximal end segment a passthrough opening (42) for the hollow needle (12), and in its proximal end position substantially conceals the hollow needle (12);

having a compression spring (26), arranged between the hollow needle carrier (10) and displaceable cap (32), for displacing the cap (32) into said proximal end position; and

having a covering cap (66) which surrounds the displaceable cap (32), the hollow needle, and the hollow needle carrier (10), and on its open side is sealed by a sealing member (71) that is removable by the user.

31. The needle arrangement as defined in Claim 30, in which the covering cap (66) is configured to influence at least one stop member (58, 60, 58', 60') for adjustment of the penetration depth (D).

32. The needle arrangement as defined in Claim 31, in which the at least one stop member (58, 60) is mounted on the hollow needle carrier (10) via a defined break point (76) which can be broken off by way of a rotary motion (74) of the covering cap (66, 66') brought into engagement with said stop member.

33. The needle arrangement as defined in one or more of Claims 30 through 32, in which the sealing member removable by the user is configured as a peelable film (71).

ABSTRACT

The invention concerns a needle arrangement for an injection device (16). It has a hollow needle carrier (10) on which a hollow needle (12) is mounted and which is configured for mounting on the injection device (16). The arrangement has a cap (32) which is displaceable on the hollow needle carrier (10) approximately parallel to the longitudinal extension of the hollow needle (12), is equipped at its proximal end segment with a passthrough opening (42) for the hollow needle (12), and in its proximal end position substantially conceals the hollow needle (12). A compression spring (26) is arranged between the hollow needle carrier (10) and cap (32) in order to displace the cap (32) into its proximal end position. Also provided is a covering cap (66) which surrounds the displaceable cap (32), the hollow needle (12), and the hollow needle carrier (10), and is sealed on its open side by a sealing member (71) that is removable by the user. A needle arrangement of this kind can easily be replaced after an injection. It improves compliance because the patient does not at any time see the hollow needle (12). The compression spring can be configured as a plastic spring (26). It is preferably integral with the hollow needle carrier (10), which simplifies manufacture.

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ERKLÄRUNG FÜR PATENTANMELDUNG, MIT VOLLMACHT

GERMAN-LANGUAGE DECLARATION

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☐ hier beigefügt ist.	☐ is attached hereto.
☒ am 11. NOV. 1998 unter der PCT Anmeldungsnummer PCT/EP98/07230 (US Anwaltaktennummer 870-003-123) eingereicht wurde und am ________________ abgeandert wurde (falls tatsachlich abgeändert).	☒ was filed on 11 NOV. 1998 as PCT Application Number PCT/EP98/07230 (U.S. Att. docket 870-003-123) and was amended on (if in fact amended)
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Priorität beansprucht		Prior foreign applications	Priority claimed?	
297 20 513 7 Nummer/Number	GERMANY Land/Country	19 NOV 1997 Day/Month/Year Filed Tag/Monat/Jahr eingereicht	☒ Ja/Yes	☐ Nein/No
Nummer/Number	Land/Country	Day/Month/Year Filed Tag/Monat/Jahr eingereicht	☐ Ja/Yes	☐ Nein/No
Nummer/Number	Land/Country	Day/Month/Year Filed Tag/Monat/Jahr eingereicht	☐ Ja/Yes	☐ Nein/No

Ich beanspruche hiermit, gemäss Absatz 35 der Bundesgesetze der Vereinigten Staaten, § 120, den Vorzug aller unten angeführten Anmeldung und falls der Gegenstand aus jedem Anspruch dieser Anmeldung nicht in einer früheren amerikanischen Patentanmeldung laut dem ersten Paragraph des Absatzes 35 der Bundesgesetze der Vereinigten Staaten, § 112, offenbart ist, erkenne ich gemäss Absatz 37, Bundesvorschriften, § 1.56(a), meine Pflicht zur Offenbarung von Informationen an, die zwischen dem Anmeldedatum der früheren Anmeldung und dem nationalen oder PCT internationalen Anmeldedatum dieser Anmeldung bekannt geworden sind.	I hereby claim the benefit under Title 35, United States Code, § 120, of any United States application(s) listed below and, insofar as the subject-matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.
Anmeldenummer/Appn SN Anmeldedatum/App'n Date	Status (patented, pending, or abandoned) (patentiert, anhängig, oder aufgegeben)
09/ Anmeldenummer/Appn SN Anmeldedatum/App'n Date	Status (patented, pending, or abandoned) (patentiert, anhängig, oder aufgegeben)
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